

Claims 1, 4, 6-11 and 19-22 are rejected under 35 U.S.C. §102(b) as being anticipated by Aoyama et al. (U.S. Patent No. 5,540,842) ("Aoyama"). The positions of the Office appear to be that the granules produced by the method of Aoyama do not distinguish from the first composition of the solid preparation of the present invention and that the core particles of sugar of the second composition of the solid preparation of the present invention that are coated with the same sugar read on the glucose used to prepare the composition of Aoyama.

Claim 1 has been amended to include the limitations of claim 12. Claim 12 was not included in the 35 U.S.C. § 102 rejection. For this reason alone, removal of the rejection is in order.

However, the solid preparation for dialysis of the present invention as recited in the rejected claims differs from and does not read on the composition of Aoyama (even if claim 1 is not amended). In Aoyama, glucose is added during the preparation of the component A (corresponding to the first composition in the present invention) and is deposited on sodium chloride with other electrolyte compounds (column 3, lines 35-40). In the present invention, glucose is used as a core particle and used for forming

particles in addition to the particles formed of sodium chloride and the other electrolyte compounds. The solid preparation for dialysis of the present invention has no fear that glucose is decomposed or colored and is excellent in long-term preservation stability as compared with the preparation in Aoyama. Furthermore, the solid preparation of the present invention is excellent in content homogeneity.

For this reason also, removal of the 35 U.S.C. § 102 rejection is in order and is respectfully requested.

Claims 1, 4, 6 and 8-22 are rejected under 35 U.S.C. §103(a) as being unpatentable over EP 0399918 ("EP '918"). The Office notes that EP '918 discloses a dialysis preparation in which a first composition comprises an intimate mixture of sodium chloride and electrolytes and a second composition contains glucose and sodium hydrogen bicarbonate. The position of the Office is that it would be obvious to coat the sodium chloride of EP '918 with the electrolytes with the expectation of similar results to that of the preparation of the present invention because "it is the Examiner's position that when sodium chloride (the predominant salt of the first composition in EP) is mixed with the instant electrolytes,

the electrolytes coat the NaCl particles." (Action, page 5, lines 12-14).

The rejection is not proper. It is well-established that obviousness must come from within the teachings of the prior art. The "examiner's position" is not prior art and is totally unsupported. As recently noted by the Court of Appeals for the Federal Circuit in *In re Lee*, 277 F.3d 1338, 1341, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002):

"As applied to the determination of patentability vel non when the issue is obviousness, 'it is fundamental that rejections under 35 U.S.C. §103 must be based on evidence comprehended by the language of that section.' *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983). The essential factual evidence on the issue of obviousness is set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966) and extensive ensuing precedent. The patent examination process centers on prior art and the analysis thereof. When patentability turns on the question of obviousness, the search for and analysis of the prior art includes evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness."

It is clear from the court's statements that the Office must provide evidence of a teaching, motivation, or suggestion in the prior art to modify the EP reference as proposed by the Office. The Office has not provided proper evidence to support the 35

U.S.C. § 103(a) rejection and, for this reason alone, the 35 U.S.C. § 103(a) rejection is improper and should be removed.

Additionally, an essential difference between the present invention and the invention disclosed in EP '918 (EP 0399918) is whether sugar is covered with sugar or not. In EP '918, glucose is pulverized and mixed with sodium hydrogen carbonate and dried (page 7, lines 10-13). Since glucose in EP '918 is not covered with glucose, the particle diameter of the particles of the first composition is different from that of the particles of glucose and the obtained preparation does not have good content homogeneity. On the other hand, the sugar in the present invention is covered with a coating layer comprising a sugar. As a result of this step, the particle diameter of the sugar is approximately the same as that of the first composition and the obtained preparation is excellent in content homogeneity. No motive is provided in the prior art to coat the glucose in EP '918 with a layer of glucose.

For this reason also, the 35 U.S.C. § 103(a) rejection is improper and should be removed.

The foregoing is believed to be a complete and proper response to the Office Action dated November 21, 2002, and is believed to


place this application in condition for allowance. If, however, minor issues remain that can be resolved by means of a telephone interview, the Examiner is respectfully requested to contact the undersigned attorney at the telephone number indicated below.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attachment is captioned **"VERSION WITH MARKINGS TO SHOW CHANGES MADE."**

In the event that this paper is not considered to be timely filed, applicants hereby petition for an appropriate extension of time. The fee for any such extension may be charged to our Deposit Account No. 111833.

In the event any additional fees are required, please also charge our Deposit Account No. 111833.

Respectfully submitted,  
KUBOVCIK & KUBOVCIK



Ronald J. Kubovcik  
Reg. No. 25,401

Atty. Case No. NPR-085  
The Farragut Building  
Suite 710  
900 17th Street, N.W.  
Washington, D.C. 20006  
Tel: (202) 887-9023  
Fax: (202) 887-9093

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 12 has been canceled.

Claim 1 has been amended as follows:

1.     **(Twice Amended)**     A solid preparation for dialysis comprising a mixture of (1) particles of a first composition comprising core particles comprising particles of sodium chloride, and a coating layer covering the core particles and containing one or more electrolytes selected from the group consisting of calcium chloride, magnesium chloride, potassium chloride and sodium acetate and up to 50% by weight of sodium chloride, (2) particles of a second composition comprising core particles comprising particles of a sugar, the core particles being covered with a coating layer comprising said sugar or a different sugar, and (3) an acid.